

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

ECKHARD U. ALT, MD

Plaintiff

vs.

MEDTRONIC, INC., a Minnesota Corp.

Defendant

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CASE NO. 2:04-CV-370

MEMORANDUM OPINION

This claim construction Memorandum Opinion construes terms in U.S. Patent Nos. 5,014,700 (“the ‘4,700 patent”), 5,031,615 (“the ‘615 patent”), 6,076,014 (“the ‘014 patent”), and 6,249,700 (“the ‘9,700 patent”).

BACKGROUND

Dr. Eckhard U. Alt (“Alt”) alleges that Medtronic, Inc. (“Medtronic”) infringes four of his patents. The ‘4,700 patent discloses a pacemaker capable of detecting motion, distinguishing movements generated by physical exercise and those not related to physical exercise, and correspondingly adjusting its pacing rate in increments complementary to the patient’s physical activity level. The ‘615 patent discloses a pacemaker with the same functionality as the ‘4,700 patent, but adds a miniaturized accelerometer and semiconductor device to detect movements related to physical exercise and to generate the appropriate level of stimulation to control the heart’s pulsing rate. The ‘014 patent discloses a defibrillator integrated with a pacemaker that utilizes the motion sensing capabilities of both the ‘4,700 and ‘615 patents. The ‘9,700 patent discloses the same integrated defibrillator and pacemaker functions as the ‘014 patent and adds the capability to

decrease defibrillating¹ and cardioverting² functions by reducing the pacing rate during prolonged periods of rest, which increases the battery life of the implanted device.

APPLICABLE LAW

“It is a ‘bedrock principle’ of patent law that ‘the claims of a patent define the invention to which the patentee is entitled the right to exclude.’” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting *Innova/Pure Water Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). In claim construction, courts examine the patent’s intrinsic evidence to define the patented invention’s scope. *See id.*; *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 861 (Fed. Cir. 2004); *Bell Atl. Network Servs., Inc. v. Covad Communications Group, Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001). This intrinsic evidence includes the claims themselves, the specification, and the prosecution history. *See Phillips*, 415 F.3d at 1314; *C.R. Bard, Inc.*, 388 F.3d at 861. Courts give claim terms their ordinary and accustomed meaning as understood by one of ordinary skill in the art at the time of the invention in the context of the entire patent. *Phillips*, 415 F.3d at 1312-13; *Alloc, Inc. v. Int’l Trade Comm’n*, 342 F.3d 1361, 1368 (Fed. Cir. 2003).

The claims themselves provide substantial guidance in determining the meaning of particular claim terms. *Phillips*, 415 F.3d at 1314. First, a term’s context in the asserted claim can be very instructive. *Id.* Other asserted or unasserted claims can also aid in determining the claim’s meaning because claim terms are typically used consistently throughout the patent. *Id.* Differences among the claim terms can also assist in understanding a term’s meaning. *Id.* For example, when a dependent claim adds a limitation to an independent claim, it is presumed that the independent claim

¹Defibrillation is the restoration of normal rhythm to a heart having irregular contractions of the muscle fibers.

² Cardioversion is the application of an electrical shock to a heart to restore a normal heartbeat.

does not include the limitation. *Id.* at 1314-15.

Claims “must be read in view of the specification, of which they are a part.” *Id.* (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978 (Fed. Cir. 1995)). “[T]he specification ‘is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.’” *Id.* (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)); *Teleflex, Inc. v. Ficoso N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002). This is true because a patentee may define his own terms, give a claim term a different meaning than the term would otherwise possess, or disclaim or disavow the claim scope. *Phillips*, 415 F.3d at 1316. In these situations, the inventor’s lexicography governs. *Id.* Also, the specification may resolve ambiguous claim terms “where the ordinary and accustomed meaning of the words used in the claims lack sufficient clarity to permit the scope of the claim to be ascertained from the words alone.” *Teleflex, Inc.*, 299 F.3d at 1325. But, “although the specification may aid the court in interpreting the meaning of disputed claim language, particular embodiments and examples appearing in the specification will not generally be read into the claims.” *Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed. Cir. 1998); *see also Phillips*, 415 F.3d at 1323. The prosecution history is another tool to supply the proper context for claim construction because a patent applicant may also define a term in prosecuting the patent. *Home Diagnostics, Inc., v. Lifescan, Inc.*, 381 F.3d 1352, 1356 (Fed. Cir. 2004) (“As in the case of the specification, a patent applicant may define a term in prosecuting a patent.”).

Although extrinsic evidence can be useful, it is “less significant than the intrinsic record in determining ‘the legally operative meaning of claim language.’” *Phillips*, 415 F.3d at 1317 (quoting *C.R. Bard, Inc.*, 388 F.3d at 862). Technical dictionaries and treatises may help a court understand the underlying technology and the manner in which one skilled in the art might use claim terms, but

technical dictionaries and treatises may provide definitions that are too broad or may not be indicative of how the term is used in the patent. *Id.* at 1318. Similarly, expert testimony may aid a court in understanding the underlying technology and determining the particular meaning of a term in the pertinent field, but an expert's conclusory, unsupported assertions as to a term's definition is entirely unhelpful to a court. *Id.* Generally, extrinsic evidence is "less reliable than the patent and its prosecution history in determining how to read claim terms." *Id.*

The patents in suit also contain means-plus-function limitations that require construction. Where a claim limitation is expressed in "means plus function" language and does not recite definite structure in support of its function, the limitation is subject to 35 U.S.C. § 112, ¶ 6. *Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1424 (Fed. Cir. 1997). In relevant part, 35 U.S.C. § 112, ¶ 6 mandates that "such a claim limitation 'be construed to cover the corresponding structure . . . described in the specification and equivalents thereof.'" *Id.* (citing 35 U.S.C. § 112, ¶ 6). Accordingly, when faced with means-plus-function limitations, courts "must turn to the written description of the patent to find the structure that corresponds to the means recited in the [limitations]." *Id.*

Construing a means-plus-function limitation involves multiple inquiries. "The first step in construing [a means-plus-function] limitation is a determination of the function of the means-plus-function limitation." *Medtronic, Inc. v. Advanced Cardiovascular Sys., Inc.*, 248 F.3d 1303, 1311 (Fed. Cir. 2001). Once a court has determined the limitation's function, "the next step is to determine the corresponding structure disclosed in the specification and equivalents thereof." *Id.* A "structure disclosed in the specification is 'corresponding' structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim." *Id.* Moreover, the focus of the "corresponding structure" inquiry is not merely whether a structure is

capable of performing the recited function, but rather whether the corresponding structure is “clearly linked or associated with the [recited] function.” *Id.*

THE ‘4700 PATENT³

As previously stated, the ‘4,700 patent discloses a pacemaker capable of detecting motion, distinguishing movements generated by physical exercise, and those not related to physical exercise and correspondingly adjusting its pacing rate in increments complementary to the patient’s physical activity level.

Means for detecting movement of the patient

The parties do not dispute that this limitation should be construed as a means-plus-function limitation under 35 U.S.C. § 112, ¶ 6. Furthermore, the parties and the Court agree that the claimed function is “detecting movements of the patient” and the corresponding structure is the “activity sensor 3 (e.g., an accelerometer) or its equivalent.”

Means responsive to the detected movements for discriminating between those of said detected movements which are indicative of physical exercise by the patient and those of said detected movements which are attributable to other than physical exercise.

The parties do not dispute that this limitation should be construed as a means-plus-function limitation under 35 U.S.C. § 112, ¶ 6. The parties and the Court agree that the claimed function is “responding to detected movements for discriminating between those of said detected movements which are indicative of physical exercise by the patient and those of said detected movements which are attributable to other than physical exercise.” The Court modifies Medtronic’s proposed structure and construes the corresponding structure as the “bandpass filter circuit that senses only frequencies from about 0.3 Hz up to about 4 Hz as shown in Figure 2a that occur over normal ranges of patient

³ Appendix A contains the relevant claims of all the patents with the disputed terms in italics.

activity levels or fabricated frequency limits in the activity sensing mechanoelectrical transducer 3 of Figure 1 so that it senses only frequencies within these same limits for the same activity ranges, and equivalents thereof.”

Alt’s proposed corresponding structure is “evaluation circuit 10a or its equivalent,” which excludes mention of the bandpass filter. Medtronic argues that the specification consistently mentions evaluation circuit 10a in conjunction with the bandpass filter. *E.g.*, Col. 9:66-67, 11:46, 12:7-9, 12:49-51. Furthermore, Medtronic contends that evaluation circuit 10a is not capable of performing the recited “discriminating” function without the bandpass filter because circuit 10a merely causes values to be “averaged” and does not limit the frequency signal as taught in the patent. *See* Col. 9:59. The Court agrees with Medtronic, that the bandpass filter is the only structure that can perform the function of “discriminating” movements and, therefore, that evaluation circuit 10a is incapable of performing the related function on its own.

Alt argues that the specific frequency range, 0.3 Hz to 4 Hz, should not be imported into the corresponding structure. Medtronic contends that the frequency range is a characteristic specifically taught in the specification and file history to discriminate between exercise and other movements. *See* Col. 8:62-9:2, 9:17-23; Supplemental Amendment 6/23/89 p.7; Amendment 04/05/89, pp. 12-13; Amendment 11/08/90, p.11. The Court agrees with Medtronic to the extent that the frequency range limitation is a characteristic of the structure spelled out in the specification. However, the Court does not limit the frequency to a strict range of 0.3 Hz to 4 Hz. The structure’s function is to discriminate between movements related to exercise and non-exercise related movements. Although the patent teaches that a structure with a frequency range limit from about 0.3 Hz to about 4 Hz will accomplish this function, it does not limit the hertz range to these exact numbers. A different range may more accurately discriminate between movements related to exercise and non-exercise related

movements. Therefore, the Court construes the range as “from about 0.3 Hz up to about 4Hz.”

Discriminating between those of said detected movements which are indicative of physical exercise by the patient and those of said detected movements which are attributable to other than physical exercise

The Court agrees with Alt that this term does not require construction. Medtronic argues that the term should be construed to include a 0.3 Hz to 4 Hz frequency limitation because of statements made in the patent specification and prosecution history. *See* Col. 3:58-67, 4:14-18; Supplemental Amendment 06/23/89, p.7; Amendment, 04/05/89, pp.12-13; Supplemental Amendment 06/23/89, p.9. The statements in the specification and prosecution history do not place a further limitation on this claim language. The hertz range of 0.3 Hz to 4 Hz is not linked to this claim language in the same manner that it is linked to the structure discussed in the above construction.

Means responsive to said detected movements indicative of physical exercise for incrementally adjusting the rate of said pacemaker according to the level of said physical exercise

The parties do not dispute that this limitation should be construed as a means-plus-function limitation under 35 U.S.C. § 112, ¶ 6. The Court adopts Medtronic’s proposed construction and construes the function as “incrementally adjusting the rate of said pacemaker according to the level of said physical exercise.” Alt argues that the function should be construed as “responding to said detected movements indicative of physical exercise.” Alt argues that the specification identifies “logic circuit 12,” the undisputed corresponding structure, as the structure that performs the function of “responding to said detected movements indicative of physical exercise.” *See* Col. 8:9-24, 10:20-30. Medtronic cites *Intellectual Property Development, Inc. v. UA-Columbia Cablevision of Westchester, Inc.*, 336 F.3d 1308, 1319 (Fed. Cir. 2003), arguing that the language “responsive to” in the claim does not indicate functional language but indicates a relationship between the means for incrementally adjusting the rate of said pacemaker and detected movements indicative of physical

exercise. Furthermore, Medtronic cites *Micro Chemical, Inc. v. Great Plains Chemical Co.*, 194 F.3d 1250, 1258 (Fed. Cir. 1999), arguing that the preposition “for” in claim language is a statutory signal under §112, ¶ 6 identifying the start of the function. The Court is persuaded by Medtronic’s arguments. The claim language exemplifies a traditional means-plus-function limitation. Accordingly, the Court takes a common sense approach and reads the limitation as a “means . . . for incrementally adjusting the rate of said pacemaker according to the level of said physical exercise.” “Responsive to said detected movements indicative of physical exercise” does not describe what function is performed, but rather how the function is performed.

The Court agrees with Alt that the corresponding structure should be construed as “logic circuit 12 or its equivalent.” Medtronic does not disagree that the corresponding structure is logic circuit 12. However, Medtronic argues that the structure should be construed to include an algorithm configured or programed into the logic circuit. Medtronic relies on *Harris Corp. v. Ericsson, Inc.*, 417 F.3d 1241, 1253 (Fed. Cir. 2005) for the proposition that “[a] computer-implemented means-plus-function term is limited to the corresponding structure disclosed in the specification and equivalents thereof, and the corresponding structure is the algorithm.” In *Ericsson*, the Federal Circuit held that the corresponding structure of the “time domain processing means” should have been construed to incorporate the algorithm disclosed in the specification. 417 F.3d at 1254. The microprocessor that comprised the corresponding structure was described in the specification as a microprocessor programmed to carry out the disclosed algorithm. *See id.* Therefore, the microprocessor was of a programable nature. Citing *Faroudja Laboratories, Inc. v. Dwin Electronics, Inc.*, 76 F. Supp. 2d 999 (N.D. Cal. 1999), Alt contends that *Ericsson* applies the rare situation described in *WMS Gaming, Inc. v. International Game Technology*, 184 F.3d 1339 (Fed. Cir. 1999), which does not apply to the construction of logic circuit 12. In *Faroudja*

Laboratories, the court found that the holding in *WMS Gaming* only applies in special cases where a general computer or microprocessor's structure is altered due to its programable nature. 76 F. Supp. 2d at 1016. Only when a general computer or microprocessor's structure can be altered must the court "construe the structural element to include only the structure programmed to perform the particular disclosed function." *Id.* In *Faroudja*, the district court further stated that "[t]he Federal Circuit's decision [in *WMS Gaming*] does not lead to the conclusion that a court must, as a routine matter, limit the structural element to its functional purpose by importing functional language into the structure specification." *Id.* at 1010. Unlike the microprocessors in *Ericsson* and *WMS Gaming*, Logic circuit 12 is a special purpose circuit and is not of a programable nature. Furthermore, the functionality of logic circuit 12 is sufficiently described in the specification. This case does not involve a situation where the structure should be construed to include the algorithm.

Incrementally adjusting the rate of said pacemaker according to the level of said physical exercise and incrementally adjusting

The Court agrees with Alt that this phrase and the included term "incrementally adjusting" do not require construction. Medtronic contends that the prosecution history and specification limit the scope of the phrase and the term. Medtronic argues that "incrementally adjusting" requires adjusting the pacing rate in steps and not continuously along a programmed line. *See* Amendment 1/08/90, p. 15; Amendment 06/23/89, p. 9; Col. 5:38-40. Furthermore, Medtronic argues that the specification and prosecution history indicate that the claim should be limited so that rate adjustments must be based on amplitude relative to the current threshold. *See* Col. 4:66-5:2; Comments on Statements of Reasons for Allowance, 02/02/90, p.3; Col. 12:14-24; Supplemental Amendment 06/23/89, p.7. Medtronic's arguments are not persuasive. Alt contends that the phrase contains no terms that a jury would not understand and that its meaning is self-evident. The Court

agrees with Alt and, therefore, does not construe the phrase or the included term.

THE '615 PATENT

As previously stated, the '615 patent discloses a pacemaker with the same functionality as the '4,700 patent, but adds a miniaturized accelerometer and semiconductor device to detect movements related to physical exercise and to generate the appropriate level of stimulation to control the heart's pulsing rate.

Rate selecting means within said housing for adjusting the pulse rate of said pulse generating means to stimulate the patent's heart at a physiologically appropriate rate.

The parties do not dispute that this limitation should be construed as a means-plus-function limitation under 35 U.S.C. § 112, ¶ 6. Furthermore, the parties and the Court agree that the function should be construed as “adjusting the pulse rate of said pulse generating means to stimulate the patient's heart at a physiologically appropriate rate.”

The Court agrees with Alt that the corresponding structure should be construed as “rate control 21 or its equivalent.” Medtronic argues that logic circuit 12, not rate control 21, adjusts the pulse rate of the pulse generator. Medtronic relies on language in the specification that states, “logic circuit 12 controllably initiates an increase in the rate” and contends that rate control 21 merely implements a timing function under the control of logic circuit 12. *See* Col. 10:21-22, 10:28-34, 10:43-49. Alt points to language in the specification that states, “pulse generator 9 is adjusted via rate controller 21, under the control of logic circuit 12, to increase the pacing rate” Col. 12:11-12. The language cited by Alt indicates that rate control 21 is the corresponding structure. Although logic circuit 12 controls rate control 21, it is rate control 21 that actually adjusts the pulse rate of the pulse generator.

Adjustable rate pulse generating means

The parties agree that the claimed function is “generating pulses at adjustable rates” and the corresponding structure is “pulse generator 9 of Figure 1 and equivalents thereof.” The Court has no objections to the parties’ agreed construction.

Activity sensor means arranged and adapted to be implanted in the patient to respond to movements of the patient for conversion thereof into a rate determining signal to be applied to said rate selecting means

The parties do not dispute that this limitation should be construed as a means-plus-function limitation under 35 U.S.C. § 112, ¶ 6. The Court agrees with Alt and construes the function as “responding to movement of the patient for conversion thereof into a rate determining signal to be applied to said rate selecting means.” Medtronic cites *Micro Chemical*, 194 F.3d at 1258, arguing that the word “for” in the claim phrase identifies the start of the function and that the language preceding the word “for” should not be included in the construction of the function. Alt points to language in the specification that states, “in response to detection of the rhythmical movement, the activity sensor generates a signal The signal is then processed to calculate the average difference between amplitude maxima and minima for a sequence of samples over the selected time interval.” Col. 12:48-54. The specification is instructive and indicates that the activity sensor must respond to the movements of the patient first, before it can convert the movements into a rate determining signal.

Furthermore, unlike the means for incrementally adjusting limitation of the ‘4,700 patent discussed above, the claim language does not exemplify a traditional means-plus-function limitation. The claim language uses the word “for,” but it does not read “means . . . for converting . . .” as it would if it were a traditional means-plus-function limitation. Instead, it describes an “[a]ctivity sensor means . . . to respond to movements of the patient for conversion thereof” The word

“thereof” refers back to the movement of the patient that the activity sensor responded to. Here, unlike the “responsive to” phrase in the means for incrementally adjusting limitation of the ‘4,700 patent, the “to respond to” phrase does not describe how the function is performed. Instead, it describes part of the function, which the claim language and the specification indicate necessarily involves responding to movement. It would not make sense to construe an activity sensor’s function and exclude its ability to respond to movement. Accordingly, the Court construes the function to include “responding to the movement of the patient.”

The Court modifies Medtronic’s corresponding structure and construes it to include “activity sensing mechanoelectrical transducer 3 of Figure 1 either fabricated to sense only frequencies from about 0.3 Hz up to about 4 Hz as shown in Figure 2a that occur over a normal range of patient activity levels or coupled to a bandpass filter circuit with these same frequency limits for the same activity range and equivalents thereof.” Alt argues that the frequency range should not be included in the corresponding structure because it is the function of a preferred embodiment and not a limitation on the corresponding structure. Alt cites *Micro Chemical*, 194 F.3d at 1258, arguing that the frequency range is not necessary to perform the corresponding function. Medtronic contends that the frequency range is a structural characteristic included in the only embodiment of the invention and that the range is emphasized in the specification and repeatedly used in the prosecution history to distinguish the patent from the prior art. As with the ‘4,700 patent above, the Court agrees with Medtronic to the extent that the frequency range limitation is a characteristic of the structure. However, the Court does not limit the frequency to a strict 0.3 Hz to 4 Hz range. The structure’s function is to respond to movements of the patient. This function requires that the structure make a determination of whether movements are related to physical exercise or not. Although the patent teaches that a structure with a frequency range limit from about 0.3 Hz to about 4 Hz will accomplish

this function, it does not limit the range to these exact numbers. A different range may more accurately discriminate between movements related to exercise and non-exercise related movements.

Therefore, the Court construes the range as “from about 0.3 Hz up to about 4Hz.”

Miniaturized accelerometer means . . . for generating said rate determining signal

The parties and the Court agree that this phrase does not require construction.

Integrated within hybrid electronic circuitry

The Court modifies Medtronic’s construction and construes the term as “requires that the activity sensor and other processing circuitry be formed within the same silicon chip.” Alt argues that the specification and prosecution history do not impart a special meaning to the terms “integrated” and “hybrid electronic circuitry.” Alt looks to the Webster’s Dictionary definition of “integrate” and the IEEE Standard Dictionary definition of “hybrid circuit,” combines the definitions, and construes the phrase as “incorporated within an electronic circuit that is made up of discrete components and integrated circuits.”

Medtronic looks to the specification and the prosecution history to support its construction of the phrase. Medtronic argues that “integrated” signifies an “integrated circuit,” in which the activity sensor is formed in the same silicon chip as the signal processing circuitry. In support of its argument, Medtronic points to the specification, which states, “According to a feature of the invention, the mechanoelectrical transducer [i.e., activity sensor] is . . . integrated with signal processing circuitry in a silicon chip. The integrated circuit is manufactured using conventional semiconductor process technology.” Col. 6:46-51. Furthermore, Medtronic points to language in the prosecution history used by Alt to distinguish the ‘615 patent from the prior art, which states, “Since the sensor of the present pacemaker is integrated into the evaluation and processor circuitry, . . .” Amendment, 04/05/89, pp.14-15. The specification and prosecution history are persuasive,

and the Court agrees with Medtronic's construction of the term "integrated."

Medtronic also contends that the phrase should be construed to include the definition of "hybrid circuitry." Medtronic looks to the IEEE Standard Dictionary definition of "hybrid circuitry" defined as "[a] circuit that uses a combination of digital and analog components." The word hybrid is not defined or referred to in the specification. Furthermore, nothing in the patent indicates that the term has a meaning other than its ordinary and customary meaning understood by a person of ordinary skill in the art at the time of the invention. Therefore, the definition is not incorporated into the phrase's construction.

THE '014 PATENT

As previously stated, the '014 patent discloses a defibrillator integrated with a pacemaker that utilizes the motion sensing capabilities of both the '4,700 and '615 patents.

Electrode means for continuously sensing and pacing atrial and ventricular chambers to maintain AV synchrony

The parties agree that this limitation should be construed as a means-plus-function limitation under 35 U.S.C. § 112, ¶ 6. The parties and the Court agree that the function should be construed as "continuously sensing and pacing atrial and ventricular chambers to maintain AV synchrony." Furthermore, the parties and the Court agree that the corresponding structure is "lead 22 and its associated distal tip electrode 32 for the atrium and lead 27 and its associated distal tip electrode 35 for the ventricle and equivalents thereof."

Sensor means to generate a rate adaptive pacing signal to vary the stimulation rate of a patient's heart according to the patient's need

The term is expressed in classic "means" form and consequently creates a presumption that it is subject to construction under 35 U.S.C. § 112, ¶ 6. Alt argues that the term should not be treated as a means-plus-function element under § 112, ¶ 6 because the term connotes sufficient structure to

someone of ordinary skill in the art. Medtronic argues that although the word “sensor” gives a connotation, it alone is insufficient to perform the function of “generating a rate adaptive pacing signal.” The Court agrees with Medtronic that the claim language does not provide sufficient structure to perform the function and is subject to construction under §112, ¶ 6. *See Allen Eng’g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1347 (Fed. Cir. 2002) (stating that the presumption of §112, ¶ 6 created by the word “means” is not overcome if a claim recites a function but does not recite sufficient structure to perform that function).

The Court agrees with Alt’s proposed function and construes the function as “generating a rate adaptive pacing signal.” Medtronic argues that the function should also include the language “to vary stimulation rate of a patient’s heart according to the patient’s need.” Alt contends that the specification clarifies that the sensor means do generate a rate adaptive signal but that a different module, other than the sensor means, may vary the stimulation rate of the patient’s heart in response to a rate adaptive pacing signal. Col. 10:55-58. The Court agrees with Alt’s reading of the specification.

The Court also agrees with Alt’s proposed structure and construes the corresponding structure as “accelerometer 40 or its equivalent.” Medtronic argues that the corresponding structure should also include “rate control 81” because an accelerometer alone cannot generate a pacing signal. Alt, in turn, points to the specification to support his argument. The specification states, “In a rate-adaptive (DDD-R) pacing mode, the accelerometer sensor signal is used to control the rate at which pacing pulses are generated by the signal generator 14” Col. 7:30-35. The specification also indicates that accelerometer 40 provides the rate adaptive pacing capability. See Col. 7:44-8.

Medtronic also argues that rate control 81 and accelerometer 40 are linked because the ‘014 patent incorporates the ‘614 patent by reference. Alt points to the fact that the specification of the

'014 patent does not burden accelerometer 40 with the '614 patent's structural limitations, but instead looks to the '614 patent's accelerometer as an example of a "suitable structure." Col. 7:23-25. Incorporation by reference occurs when the referencing patent makes it "apparent that the cited document is part of the referencing document as it [sic] it were fully set out therein." *In re Lund*, 376 F.2d 982, 989 (C.C.P.A. 1967). The language in the '014 patent merely refers to an example of a structure in the '614 patent and does not indicate that the '614 patent was incorporated by reference.

Defibrillator means in combination with said pacemaker for treating arrhythmias including fibrillation

The parties and the Court agree that this term does not require construction under 35 U.S.C. §112, ¶ 6. Furthermore, the parties and the Court agree that the term should be construed as "an implanted defibrillator is a small automatic device that detects and treats arrhythmias including fibrillation."

Evaluation means operatively combining said DDD-R pacemaker and said defibrillator means for developing generalized findings indicative of the apparent presence of a specific arrhythmia of the atrial or ventricular chamber from sensed signals therefrom by which to assess appropriate treatment therapy for the indicated arrhythmia

The parties do not dispute that this limitation should be construed as a means-plus-function limitation under 35 U.S.C. § 112, ¶ 6. Furthermore, the parties agree that the claimed function is "developing generalized findings indicative of the apparent presence of a specific arrhythmia of the atrial or ventricular chamber from sensed signals therefrom by which to assess appropriate treatment therapy for the indicated arrhythmia." The Court modifies Medtronic's construction of the corresponding structure and construes it as "logic 73 in Figure 3 composed of atrial evaluation logic 55, ventricle evaluation logic 56, and activity evaluation logic 58, and equivalents thereof." Alt agrees to this construction. Medtronic argues that the structure should include the algorithm

programmed in logic 73. Again, as with logic circuit 12 in the '4700 patent, Medtronic cites *Ericsson* to argue that the corresponding structure is the algorithm. *See* 417 F.3d at 1253. Alt argues that the “evaluation means” do not require the algorithm to perform the claimed function. Alt contends that the '014 patent specification teaches the claimed function independently of the use of the algorithm included in Medtronic’s corresponding structure. *Compare* Col. 2:17-65 with 3:40-49. Alt’s argument is persuasive. The structure should not be limited by the algorithm.

Generalized findings

The Court rejects both parties’ proposed constructions and finds that the term “generalized findings” does not require construction. Alt argues that the term should be defined as “clinically significant observations involving the whole of an organ.” Medtronic contends that the term should be defined as “degrees of truth used in fuzzy logic.” Neither party’s construction adds clarity to the term. The term is unambiguous and, therefore, does not require construction.

Means for limiting ventricular rate response of the heart to avoid an excessively high ventricular rate attributable to an atrial arrhythmia

The parties agree that this limitation should be construed as a means-plus-function limitation under 35 U.S.C. § 112, ¶ 6. The Court agrees with Alt and construes the claimed function as “limiting ventricular rate response of the heart.” Medtronic argues that the function should include the clause “to avoid an excessively high ventricular rate attributable to an atrial arrhythmia.” A phrase beginning with the word “for” indicates the beginning of the claimed function. *Micro Chem.*, 194 F.3d at 1258. Here, the phrase beginning with the word “for” ends and there is no indication in the patent that the phrase beginning with the word “to,” included in the function by Medtronic, should also be included in the claimed function.

The Court also agrees with Alt’s construction and construes the corresponding structure as

“rate control 81 or its equivalent.” Medtronic argues that the corresponding structure is the “structure identified for the evaluation means of claim 21 configured to establish a ventricular tracking limit tied to the activity sensor while maintaining atrial tracking.” Medtronic bases its argument on language in the specification that discusses the importance of establishing a ventricular tracking limit to achieve an atrial triggered rate controlled by the sensor to then limit the ventricular rate response. *See* Col. 7:62-8:2. This language discusses the ventricular rate response but does not indicate a structure necessary to perform the function of limiting the ventricular rate response. However, Alt cites language in the specification that indicates rate control 81 is the structure that “limit[s] the ventricular rate response of the heart.” *See* Col. 10:55-58. The specification language cited by Alt is more persuasive because it specifically points to a corresponding structure, rate control 81, to perform the claimed function.

THE ‘9,700 PATENT

As previously stated, the ‘9,700 patent discloses the same integrated defibrillator and pacemaker functions as the ‘014 patent and adds the capability to decrease defibrillating and cardioverting functions by reducing the pacing rate during prolonged periods of rest, which increases the battery life of the implanted device.

Optimizer for substantially matching the patient’s heart rate to hemodynamic demand under conditions of physical activity and rest of the patient

The Court agrees with Alt that this claim limitation should not be construed as a means-plus-function limitation under 35 U.S.C. § 112, ¶ 6. A claim term that does not use the word “means” gives rise to a rebuttable presumption that § 112, ¶ 6 does not apply. *Lighting World, Inc. v. Birchwood Lighting, Inc.*, 328 F.3d 1354, 1358 (Fed. Cir. 2004) (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 228 F.3d 1359, 1369 (Fed. Cir. 2002)). “The presumption flowing from the

absence of the term ‘means’ is a strong one that is not readily overcome.” *Id.* The presumption can be overcome “if it is demonstrated that ‘the claim term fails to recite sufficiently definite structure’ or else ‘recites function without reciting sufficient structure for performing that function.’” *Id.* (citing *CCS Fitness*, 228 F.3d at 1369). Medtronic has not overcome this presumption. Claim 15 provides sufficient structure to perform the claimed function. The claim names “optimizer” as the structure that performs the recited function. *See* Col. 13:41-14:3. Furthermore, the claim goes on to indicate two structures that make up the optimizer, the “second sensor” and “signal processor,” and how those structures act to perform the claimed function. *See id.* Therefore, the claim is not subject to §112, ¶6. *See TurboCare Div. of Demag Delaval Turbomachinery Corp. v. Gen. Elec. Co.*, 264 F.3d 1111, 1120-21 (Fed. Cir. 2001) (holding that a term was not subject to §112, ¶6 because the claim identified two structures for achieving the claimed function and then described how those structures achieved the claimed function). Similarly, due to the claim language’s thoroughness, the Court agrees with Alt that the term does not require construction.

Conditions of physical activity and rest of the patient

The parties and the Court agree that the term should be construed as “the mode or state of being active and the mode or state of having ceased work, exertion, or activity, including but not limited to sleep.”

CONCLUSION

For the foregoing reasons, the Court interprets the claim language in this case in the manner set forth above. For ease of reference, the Court’s claim interpretations are set forth in a table as Appendix B. The claims with the disputed terms in italics are set forth in Appendix A.

So ORDERED and SIGNED this 30th day of November, 2005.

A handwritten signature in black ink, appearing to read 'Leonard Davis', written over a horizontal line.

**LEONARD DAVIS
UNITED STATES DISTRICT JUDGE**

APPENDIX A

U.S. PATENT NO. 5,014,700

1. An implantable variable rate pacemaker adaptive to patient exercise, comprising:

means for detecting movements of the patient,

means responsive to the detected movements for discriminating between those of said detected movements which are indicative of physical exercise by the patient and those of said detected movements which are attributable to other than physical exercise, and

means responsive to said detected movements indicative of physical exercise for incrementally adjusting the rate of said pacemaker according to the level of said physical exercise.

U.S. PATENT NO. 5,031,615

14. In combination with an activity-sensing cardiac pacemaker for implantation in a patient, said pacemaker having a housing and adjustable rate pulse generating means and *rate selecting means within said housing for adjusting the pulse rate of said pulse generating means to stimulate the patient's heart at a physiologically appropriate rate*, the improvement comprising.

activity sensor means arranged and adapted to be implanted in the patient to respond to movements of the patient for conversion thereof into a rate determining signal to be applied to said rate selecting means, said activity sensor means including miniaturized accelerometer means integrated within hybrid electronic circuitry for generating said rate determining signal.

U.S. PATENT NO. 6,076,014

21. An implantable defibrillator device, comprising:

a DDD-R mode pacemaker having electrode means for continuously sensing and pacing atrial and ventricular chambers to maintain AV synchrony, and *sensor means to generate a rate adaptive pacing signal to vary stimulation rate of a patient's heart according to the patient's need,*

defibrillator means in combination with said pacemaker, for treating arrhythmias including fibrillation; and

evaluation means operatively combining said DDD-R pacemaker and said defibrillator means for developing generalized findings indicative of the apparent presence of a specific arrhythmia of the atrial or ventricular chamber from sensed signals therefrom by which to assess appropriate treatment therapy for the indicated arrhythmia.

22. The implantable defibrillator device of claim 21, wherein said pacemaker includes *means for limiting ventricular rate response of the heart to avoid an excessively high ventricular rate attributable to an atrial arrhythmia.*

U.S. PATENT NO. 6,249,700

15. An implantable medical interventional device for responding to detection of any of a plurality of cardiac dysrhythmias in a human patient by performing an appropriate therapy including cardiac pacing, cardioversion or defibrillation according to the nature of the detected dysrhythmia, said device comprising:

a first sensor for detecting any of said plurality of cardiac dysrhythmias;

a generator of pacing pulses and electrical shocks for delivery to the patient's heart according to whether a detected dysrhythmia is bradycardia or a relatively slow pathologic tachycardia on the one hand, or a relatively fast tachycardia or fibrillation on the other hand; and

an optimizer for substantially matching the patient's heart rate to hemodynamic demand under conditions of physical activity and rest of the patient, including:

a second sensor for sensing periods of patient activity and rest as imposing different hemodynamic demands on the patient's cardiovascular system, and for producing a signal representative of applicable hemodynamic demand, and

a signal processor for said second sensor signal to detect physical activity of the patient and the extent thereof, and for applying the processed signal to said generator to vary the pacing rate to conform to the patient's hemodynamic demand.

APPENDIX B

CLAIMS CONSTRUCTION FOR US PATENT NO. 5,014,700

Claim Language	Court's Construction
<p>1. An implantable variable rate pacemaker adaptive to patient exercise, comprising:</p> <p><i>means for detecting movements of the patient,</i></p>	<p>means for detecting movements of the patient:</p> <p><u>Function:</u> detecting movements of the patient</p> <p><u>Structure:</u> activity sensor 3 (e.g., an accelerometer) or its equivalent</p>
<p><i>means responsive to the detected movements for discriminating between those of said detected movements which are indicative of physical exercise by the patient and those of said detected movements which are attributable to other than physical exercise, and</i></p>	<p>means responsive to the detected movements for discriminating between those of said detected movements which are indicative of physical exercise by the patient and those of said detected movements which are attributable to other than physical exercise:</p> <p><u>Function:</u> responding to the detected movements and discriminating between those of said detected movements which are indicative of physical exercise by the patient and those of said detected movements which are attributable to other than physical exercise</p> <p><u>Structure:</u> bandpass filter circuit that senses only frequencies from about 0.3 Hz up to about 4 Hz as shown in Figure 2a that occur over normal ranges of patient activity levels or fabricated frequency limits in the activity sensing mechanoelectrical transducer 3 of Figure 1 so that it senses only frequencies within these same limits for the same activity ranges, and equivalents thereof</p>
	<p>discriminating between those of said detected movements which are indicative of physical exercise by the patient and those of said detected movements which are attributable to other than physical exercise: does not require construction</p>

<i>means responsive to said detected movements indicative of physical exercise for incrementally adjusting the rate of said pacemaker according to the level of said physical exercise.</i>	Means responsive to said detected movements indicative of physical exercise for incrementally adjusting the rate of said pacemaker according to the level of said physical exercise:
	<u>Function:</u> incrementally adjusting the rate of said pacemaker according to the level of said physical exercise
	<u>Structure:</u> logic circuit 12 or its equivalent
	incrementally adjusting the rate of said pacemaker according to the level of said physical exercise: does not require construction
	incrementally adjusting: does not require construction

CLAIMS CONSTRUCTION FOR US PATENT NO. 5,031,615

Claim Language	Court's Construction
14. In combination with an activity-sensing cardiac pacemaker for implantation in a patient, said pacemaker having a housing and <i>adjustable rate pulse generating means</i> and <i>rate selecting means within said housing for adjusting the pulse rate of said pulse generating means to stimulate the patient's heart at a physiologically appropriate rate</i> , the improvement comprising.	rate selecting means within said housing for adjusting the pulse rate of said pulse generating means to stimulate the patient's heart at a physiologically appropriate rate:
	<u>Function:</u> adjusting the pulse rate of said pulse generating means to stimulate the patient's heart at a physiologically appropriate rate <u>Structure:</u> rate control 21 or its equivalent adjustable rate pulse generating means: <u>Function:</u> generating pulses at adjustable rates <u>Structure:</u> pulse generator 9 of Figure 1 and equivalents thereof

<p><i>activity sensor means arranged and adapted to be implanted in the patient to respond to movements of the patient for conversion thereof into a rate determining signal to be applied to said rate selecting means, and activity sensor means including miniaturized accelerometer means integrated within hybrid electronic circuitry for generating said rate determining signal.</i></p>	<p>activity sensor means arranged and adapted to be implanted in the patient to respond to movements of the patient for conversion thereof into a rate determining signal to be applied to said rate selecting means:</p> <p><u>Function:</u> responding to movement of the patient for conversion thereof into a rate determining signal to be applied to said rate selecting means</p> <p><u>Structure:</u> activity sensing mechanoelectrical transducer 3 of Figure 1 either fabricated to sense only frequencies from about 0.3 Hz up to about 4 Hz as shown in Figure 2a that occur over normal range of patient activity levels or coupled to a bandpass filter circuit with these same frequency limits for the same activity range and equivalents thereof</p> <p>miniaturized accelerometer means . . . for generating said rate determining signal: does not require construction</p> <p>integrated within hybrid electronic circuitry: requires that the activity sensor and other processing circuitry be formed within the same silicon chip</p>
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CLAIMS CONSTRUCTION FOR US PATENT NO. 6,076,014

Claim Language	Court's Construction
<p>21. An implantable defibrillator device, comprising:</p> <p>a DDD-R mode pacemaker having <i>electrode means for continuously sensing and pacing atrial and ventricular chambers to maintain AV synchrony</i>, and <i>sensor means to generate a rate adaptive pacing signal to vary stimulation rate of a patient's heart according to the patient's need</i>,</p>	<p>electrode means for continuously sensing and pacing atrial and ventricular chambers to maintain AV synchrony:</p> <p><u>Function:</u> continuously sensing and pacing atrial and ventricular chambers to maintain AV synchrony</p> <p><u>Structure:</u> lead 22 and its associated distal tip electrode 32 for the atrium and lead 27 and its associated distal tip electrode 35 for the ventricle and equivalents thereof</p>

	<p>sensor means to generate a rate adaptive pacing signal to vary stimulation rate of a patient's heart according to the patient's need:</p> <p><u>Function</u>: generating a rate adaptive pacing signal</p> <p><u>Structure</u>: accelerometer 40 or its equivalent</p>
<i>defibrillator means in combination with said pacemaker, for treating arrhythmias including fibrillation; and</i>	<p>defibrillator means in combination with said pacemaker, for treating arrhythmias including fibrillation: an implanted defibrillator is a small automatic device that detects and treats arrhythmias including fibrillation</p>
<i>evaluation means operatively combining said DDD-R pacemaker and said defibrillator means for developing generalized findings indicative of the apparent presence of a specific arrhythmia of the atrial or ventricular chamber from sensed signals therefrom by which to assess appropriate treatment therapy for the indicated arrhythmia.</i>	<p>evaluation means operatively combining said DDD-R pacemaker and said defibrillator means for developing generalized findings indicative of the apparent presence of a specific arrhythmia of the atrial or ventricular chamber from sensed signals therefrom by which to assess appropriate treatment therapy for the indicated arrhythmia:</p> <p><u>Function</u>: developing generalized findings indicative of the apparent presence of a specific arrhythmia of the atrial or ventricular chamber from sensed signals therefrom by which to assess appropriate treatment therapy for the indicated arrhythmia</p> <p><u>Structure</u>: logic 73 in Figure 3 composed of atrial evaluation logic 55, ventricle evaluation logic 56, and activity evaluation logic 58, and equivalents thereof</p>
	<p>generalized findings: does not require construction</p>

<p>22. The implantable defibrillator device of claim 21, wherein said pacemaker includes <i>means for limiting ventricular rate response of the heart to avoid an excessively high ventricular rate attributable to an atrial arrhythmia.</i></p>	<p>means for limiting ventricular rate response of the heart to avoid an excessively high ventricular rate attributable to an atrial arrhythmia:</p> <p><u>Function:</u> limiting ventricular rate response of the heart</p> <p><u>Structure:</u> rate control 81 or its equivalent</p>
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CLAIMS CONSTRUCTION FOR US PATENT NO. 6,249,700

Claim Language	Court's Construction
<p>15. An implantable medical interventional device for responding to detection of any of a plurality of cardiac dysrhythmias in a human patient by performing an appropriate therapy including cardiac pacing, cardioversion or defibrillation according to the nature of the detected dysrhythmia, said device comprising:</p> <p>a first sensor for detecting any of said plurality of cardiac dysrhythmias;</p> <p>a generator of pacing pulses and electrical shocks for delivery to the patient's heart according to whether a detected dysrhythmia is bradycardia or a relatively slow pathologic tachycardia on the one hand, or a relatively fast tachycardia or fibrillation on the other hand; and</p> <p><i>an optimizer for substantially matching the patient's heart rate to hemodynamic demand under conditions of physical activity and rest of the patient, including:</i></p>	<p>optimizer for substantially matching the patient's heart rate to hemodynamic demand under conditions of physical activity and rest of the patient: not subject to § 112, ¶6 and does not require construction</p> <p>Condition of physical activity and rest of the patient: the mode or state of being active and the mode or state of having ceased work, exertion, or activity, including but not limited to sleep</p>